# OFFICE OF SPECIAL MASTERS No. 95-197V

(Filed: April 29, 1997)

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| DEVIN JOHNSON, by his mother and natural | * |
| guardian, MELANIE JOHNSON,               | * |
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| Petitioner,                              | * |
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| V.                                       | * |
|  | * |
| SECRETARY OF HEALTH AND                  | * |
| HUMAN SERVICES,                          | * |
|  | * |
| Respondent.                              | * |
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## **DECISION**

## **HASTINGS**, Special Master.

This is an action seeking an award under the National Vaccine Injury Compensation Program (see 42 U.S.C. § 300aa-10 *et seq*.<sup>(1)</sup>) on account of an injury to the petitioner, Devin Johnson. For the reasons stated below, the undersigned special master concludes that petitioner is not entitled to such an award.

I

#### THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program (hereinafter sometimes the "Vaccine Program" or the "Program"), compensation awards are made to individuals who have suffered injuries thought to be caused by certain vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showings that an individual received a vaccination covered by the statute; received it in the United States; suffered an injury thereafter; and has received no previous award or settlement on account of the injury. Finally--and the key question in most cases under the Program--the petitioner must also establish a link, either temporal or causal, between the vaccination and the injury. One method by which the petitioner may establish this link is by demonstrating the occurrence of what has been described as a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in § 300aa-14(a) -- the "Vaccine Injury Table" -- corresponding to the vaccination in question, within an applicable time period from the vaccination, also specified in the

Table. If so, the "Table Injury" is, in effect, <u>presumed</u> to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, one vaccination listed in the Vaccine Injury Table is the "DPT" inoculation (*i.e.*, diphtheria, pertussis, and tetanus), and one of the "Table Injuries" listed for that vaccination is "encephalopathy" (*i.e.*, brain injury). The Table further provides that in order for the vaccine recipient to qualify for an award, the first symptoms of such injury, or the first symptoms of a "significant aggravation" of such injury, must have been first manifested within *three days* of the inoculation. § 300aa-14(a)(I)(B).

Alternatively, if no injury falling within the Table can be shown, the petitioner may gain an award by instead showing that the vaccine recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii).

II

## **BACKGROUND FACTS**

Devin Johnson (hereinafter "Devin" or "petitioner") was born on January 8, 1993. He appeared to be a generally healthy baby for his first four months of life. On May 19, 1993, Devin received a "DPT" inoculation at the offices of his pediatrician in Maplewood, Minnesota. Four days later, on May 23, 1993, his mother took Devin to an "urgent care" facility, where she reported that he had been cranky and fussy since the 19th, with intermittent vomiting and a slight fever. A physician examined Devin and determined that he had an infection of both ears. (Ex. 9, pp. 14, 16. (2))

On the evening of the following day, May 24, Devin's parents rushed him to a hospital emergency room. Devin's father, who had been caring for the infant over the previous several hours, reported that Devin had suddenly became rigid and unresponsive minutes beforehand. (Ex. 9, pp. 34-37.) At the hospital, Devin was determined to have suffered seizures and a very significant, life-threatening brain injury. Emergency treatment was administered, removing the immediate danger to Devin's life.

Physicians at the hospital over the following days attempted to diagnose the cause for Devin's brain injury. Largely on the basis of CT and MRI images of Devin's head, they determined that Devin had suffered from, *inter alia*, "subdural hematoma," meaning an accumulation of blood in the subdural space adjacent to the brain, caused by bleeding from nearby blood vessels. The scans revealed that Devin had a "chronic" subdural hematoma, meaning that Devin had suffered bleeding into the space at least several weeks prior to the May hospitalization. (The record indicates that prior to May 24, 1993, Devin never displayed any outward symptoms of the chronic subdural hematoma, which would not be uncommon, depending on the size and severity of such a hematoma.) They also indicated that *new* bleeding into the same general area had very recently taken place, apparently causing the increased pressure on Devin's brain which resulted in his episode of rigidity, unconsciousness, and seizures on May 24.

Because of the nature of the injury, certain of Devin's physicians at the hospital questioned whether his brain injury might have been the result of intentional physical abuse. (See, *e.g.*, Ex. 10, pp. 214, 216.) A "physical abuse consultation" was conducted. (See Ex. 10, pp. 245-256.) As a result of that consultation, a physician specializing in child abuse matters, Dr. Carolyn Levitt, concluded that Devin's injury "very clearly fits" within a pattern of child abuse known as "Shaken Baby Syndrome." (Ex. 10, p. 255.) Law enforcement authorities were notified, and Devin's father, Jeffrey Lee Johnson, was criminally charged with assault and malicious punishment of the infant. After a nonjury trial, the judge acquitted Jeffrey

Johnson. (See Ex. 17; see also respondent's Exs. E and F, the transcripts of the criminal trial, filed in this proceeding on May 2, 1996.)

Since his brain injury in May of 1993, Devin has suffered significant difficulties in mental and behavioral development, which are said to be a result of that brain injury.

Ш

#### **ISSUES FOR DECISION**

In this case, there is no dispute that Devin received a DPT vaccination on May 19, 1993, in the United States, and manifested a serious brain injury (encephalopathy) no later than May 24, 1993. The issues requiring resolution here are whether petitioner has established the necessary link between Devin's brain injury manifested on May 24, 1993, and his DPT inoculation, via either of three possible theories: (1) that Devin exhibited the first manifestation of the *onset* of an "encephalopathy" within three days of his DPT inoculation on May 19, 1993; (2) that he exhibited the first manifestation of a *significant aggravation* of an encephalopathy within three days of that same DPT inoculation; or (3) that Devin's brain injury manifested on May 24, 1993, was *caused-in-fact* by his DPT inoculation. I conclude that petitioner has failed to establish entitlement to a Program award by any of these potential avenues. My reasoning will follow.

IV

# ISSUE OF "ONSET" OF "TABLE INJURY ENCEPHALOPATHY"

### A. Introduction

At the outset of the evidentiary hearing, petitioner's counsel stated that petitioner's sole theory of entitlement to an award was that Devin manifested the "significant aggravation" of the Table Injury known as "encephalopathy" within three days of his DPT inoculation on May 19, 1993. However, it soon developed that the testimony of petitioner's expert seemed to support not a *significant aggravation* theory, but rather an *onset* theory as to the encephalopathy Table Injury. That is, Dr. Schweller opined that Devin did not have an "encephalopathy" *prior* to his inoculation (Tr. 37-38), but did exhibit the *first symptoms* of an encephalopathy within three days of the inoculation. Thus, in effect, this theory of *onset* of "Table Injury encephalopathy" became the primary argument of petitioner. Therefore, I will discuss that theory first.

I will begin my discussion of this theory by presenting a general summary of the opinions of the three experts who testified at the evidentiary hearing, concerning Devin's overall course.

# B. Summary of experts' respective views

All three of the experts who testified in this case agree that prior to his DPT inoculation on May 19, 1993, Devin already had a subdural hematoma--meaning an accumulation of blood in the subdural space adjacent to the brain, caused by bleeding from nearby blood vessels--but had not suffered any major symptoms caused by that hematoma. They also agree that on May 24, 1993, when Devin was rushed to the hospital, he was suffering from the effects of a new, more serious episode of bleeding into the subdural space. They agree that the new bleeding episode resulted in greatly increased pressure within Devin's skull--*i.e.*, intracranial pressure--which resulted in the dramatic symptoms that Devin displayed that evening. As to other aspects of Devin's case, however, the three experts have radically different

views.

Dr. Thomas Schweller, a pediatric neurologist, testified for petitioner. Dr. Schweller believes that most of the symptoms that Devin displayed during the period between May 19 and May 23, including irritability, fever, and vomiting, were in fact *related* to the brain injury that Devin manifested during the evening of May 24. He opined that the blood vessels that had previously bled, causing the existing "chronic" subdural hematoma in Devin, began to bleed again *during the three-day period* after Devin's inoculation. He believes it likely that the effect of the vaccination caused that new bleeding, though he is not certain about that. This new bleeding, in Dr. Schweller's view, caused intracranial pressure that soon caused Devin discomfort, explaining the irritability and crying that Devin exhibited during this period, along with other unusual behavior that Devin may have displayed, such as being difficult to feed, being "less responsive," and displaying unusual head movements and/or head tilt. The intracranial pressure, in Dr. Schweller's view, also caused Devin's episode of vomiting described as "projectile vomiting." Dr. Schweller testified that all the symptoms described in the previous two sentences were signs of encephalopathy that were manifested by Devin within the three-day post-vaccination period.

Ultimately, Dr. Schweller testified, the new hematoma continued to cause increased intracranial pressure in Devin, resulting on May 24, 1997, in the dramatic symptoms that caused Devin's father to rush the infant to the hospital that evening.

Respondent's experts, Dr. Lawrence Lockman, a pediatric neurologist, and Dr. David Chadwick, a pediatrician who has specialized in injuries caused by child abuse, heartily disagree with Dr. Schweller. Both view the symptoms that Devin displayed between May 19 and May 23 as related to the ear infection that was diagnosed on May 23. They do not view these symptoms as evidence of encephalopathy, or as medically related to what happened to Devin on May 24. They opined that during the evening of May 24, 1997, Devin suffered some type of significant trauma that jarred his head and caused a new, significant round of bleeding into Devin's subdural space. This bleeding, in the opinion of these experts, set off a relatively quick process of brain swelling and intracranial pressure that caused symptoms that resulted in Devin's hospitalization that evening.

## C. Analysis

As to this issue, as well as the entire case, I simply did not find that Dr. Schweller made a persuasive case. I found the analysis of Drs. Lockman and Chadwick to be far more convincing.

First, I should point out that I would resolve this case in the same fashion even were there *no evidence at all* concerning the possibility that Devin was the victim of *child abuse*. That is, to demonstrate a Table Injury, it must be shown "more probable than not" that Devin manifested symptoms of encephalopathy *within three days* of his DPT inoculation. There was no such successful showing in this case. It is undisputed, of course, that Devin *did* suffer an "encephalopathy," in the expansive sense in which that term is defined in the Vaccine Injury Table. (See § 300aa-14(b)(3)(A).) The symptoms that Devin exhibited on the evening of May 24 were clearly manifestation of encephalopathy. But Dr. Schweller failed to persuade me that it is likely that the symptoms that Devin displayed during the period between May 19 and May 23 had anything to do with the encephalopathy that the infant manifested on May 24. Rather, as Drs. Lockman and Chadwick opined, it seems much more likely that the symptoms of May 19-23 were related to the *bilateral ear infection* that was in fact diagnosed in Devin on May 23.

In this regard, it is appropriate to discuss particularly Dr. Schweller's assertion that "projectile" vomiting was a symptom of encephalopathy manifested by Devin within the three-day post-vaccination period. It is true, of course, that true "projectile" vomiting can be a result of intracranial pressure, thereby suggesting the possibility of brain injury. It is also true that a nurse's note made on May 23 indicates that Devin

"vomited \* \* \* projectile," followed by the parenthetical notation "(forceful spitup)." (Ex. 9, p. 14.) However, a close reading of the record indicates that Dr. Schweller is mistaken as to the *timing* of this episode of forceful vomiting. That is, the nurse's note makes it clear that this episode took place at 7:30 a.m. on *May 23*, 1997, which was *not* within the crucial three-day period. In contrast, the other vomiting that Devin suffered during the May 19-23 period was *not* described in the medical records (6) as "projectile" or "forceful" in nature.

Moreover, Drs. Lockman and Chadwick both testified that even the one episode on the morning of May 23 was not likely an example of vomiting caused by *intracranial pressure*. Those experts explained that often vomiting that seems "forceful" is not the result of intracranial pressure, but just a more dramatic form of vomiting produced by digestive distress. Dr. Lockman's testimony was particularly persuasive on this point. He explained that if a person was having projectile vomiting caused by intracranial pressure, *all* of that person's vomiting would be projectile in nature. In other words, such person would not likely, have a single episode of "projectile" vomiting caused by intracranial pressure, surrounded by other episodes of non-forceful vomiting. Dr. Schweller did not rebut this point made by Dr. Lockman. Thus, since Devin did have a number of other episodes of non-forceful vomiting, (7) it seems *unlikely* that his one episode of forceful vomiting on the morning of May 23 was caused by intracranial pressure. (8)

Another crucial point in this regard is that Devin was in fact examined by a physician on May 23, 1993. Drs. Chadwick and Lockman testified persuasively (Dr. Lockman's testimony was particularly helpful on this point) that it seems very unlikely that, had Devin in fact been suffering from an ongoing encephalopathy at that point, the examining physician would have missed it.

In addition, both Drs. Chadwick and Lockman testified that given the nature of the dramatic symptoms that Devin exhibited on the evening of May 24, the condition in which he was found at the hospital that evening, and the results of the radiological scans of Devin's head, they found it very likely that the bleeding that resulted in the new hematoma occurred only minutes or at most a few hours before Devin was taken to the hospital on May 24. They found it quite unlikely that the bleeding process had been going on for days, as Dr. Schweller suggested. I found this testimony of Drs. Lockman and Chadwick to be persuasive, and Dr. Schweller did not respond and explain why his theory of bleeding for several days was a viable one. (9)

In short, even setting aside the evidence affirmatively appointing to trauma as the cause of the encephalopathy manifested on May 24, after reviewing the other evidence of record, I simply find that Dr. Schweller's basic theory, that Devin displayed symptoms of encephalopathy *within three days* of his May 19 inoculation, is speculative at best. There is simply a better explanation for the symptoms that Devin did display during that period-- *i.e.*, the ear infection. Moreover, there is just no persuasive evidence linking the May 19 - May 23 symptoms to the encephalopathy that Devin did manifest on May 24.

In addition, there is, of course, considerable affirmative evidence from which one could conclude that the encephalopathy that Devin manifested on May 24 was the result of *trauma*, whether from intentional abuse or accident. Drs. Chadwick and Lockman testified quite persuasively on this point, and the medical literature submitted by both sides in this case offers substantial support to their testimony. To summarize, this evidence indicates that when an infant has the particular *combination* of injuries that Devin had (*i.e.*, subdural hematoma, brain swelling, and retinal hemorrhaging (10)) such injuries are *very* likely to have been caused by physical trauma--*i.e.*, the head has hit something or been struck or been moved rapidly enough to damage the brain tissue--rather than some other cause such as disease or exposure to a toxic substance. Again, I did not find that Dr. Schweller came close to effectively rebutting the evidence in this regard.

And, as further evidence pointing to trauma as the likely cause of Devin's condition, I note that the records of Devin's hospitalization after the May 24 incident indicate that Devin's *actual treating physicians* during that hospitalization themselves strongly suspected that trauma was the cause of Devin's brain injury, while there is no evidence that such physicians considered that a *several-day process* of gradual bleeding, from any source, was the cause. See, *e.g.*, the note of Dr. Thomas (Ex. 10, p. 192) (test results are "strongly supporting" a diagnosis of "shaken baby"); discharge summary of Drs. Keller and Kim (Ex. 10, 214) (findings "very consistent with nonaccidental trauma"); note of Dr. Levitt (Ex. 10, p. 255) (Devin "very clearly fits the diagnosis of Shaken Baby Syndrome"). The opinions of these treating physicians are important, of course, because they are *not* tainted by the bias that is inherent in the opinions of the experts who are hired for the purpose of providing an opinion in a litigative setting.

In sum, all the evidence pointing to trauma as a likely cause for Devin's encephalopathy, then, adds further to the reason for rejecting the theory that his encephalopathy was the result of a gradual non-traumatic process that began within the three-day period post-vaccination.

# D. Conclusion

For all the reasons noted above, I find that petitioner has failed to demonstrate it "more likely than not" that he suffered the onset of a "Table Injury encephalopathy" within the required three-day period.

 $\mathbf{V}$ 

## ISSUE OF "SIGNIFICANT AGGRAVATION"

As previously noted, at the outset of the evidentiary hearing, petitioner's counsel stated that petitioner would demonstrate the "significant aggravation" of a "Table Injury encephalopathy." She noted that the applicable law in this regard would, therefore, include the teachings of *Whitecotton v. Secretary of HHS*, 81 F. 3d 1099 (Fed. Cir. 1996). However, petitioner's expert subsequently *denied* that Devin had experienced an "encephalopathy" *prior* to his inoculation of May 19, 1993. (See Tr. 37-38.) Therefore, it is obvious that Devin cannot have suffered the "aggravation" of an encephalopathy, if he did not have an encephalopathy to begin with.

Accordingly, I conclude that petitioner has failed to demonstrate entitlement to an award under the theory of "significant aggravation" of "encephalopathy."

I do add, however, that the mistaken suggestion as to the applicable theory by petitioner's counsel was understandable, given the unusual nature of the facts of this case. Dr. Schweller was in fact testifying, in effect, that Devin experienced in the three-day period a "significant aggravation" of his previously existing *chronic subdural hematoma*. But since a "chronic subdural hematoma" is not an injury listed in the Vaccine Injury Table, an aggravation of such an injury is *not* a Table Injury.

Finally, I note that even if a "chronic subdural hematoma," which is in effect an abnormal condition in or near the brain, were considered to be an "encephalopathy," petitioner still would not have demonstrated a "significant aggravation" of that condition compensable under *Whitecotton*. That is because under the fourth step of the *Whitecotton* test, it must be shown that the "first symptom or manifestation" of the significant worsening of the condition took place within the Table-prescribed time period, which in this case was the three-day period from vaccination. Under the facts of this case, for reasons already discussed above, even if one considers Devin's new head bleeding manifested on May 24, 1993, to be an aggravation of the previously existing chronic hematoma, the first manifestation of the significant worsening of that condition did not take place until *May 24*, which was more than three days after the vaccination.

#### "CAUSATION-IN-FACT" ISSUE

Petitioner's primary focus in this case clearly has been upon establishing the occurrence of a "Table Injury encephalopathy." But "causation-in-fact," as noted above, is an alternative method of establishing entitlement to an award. And in the course of his hearing testimony in this case, Dr. Schweller stated the opinion that the new bleeding into Devin's subdural space, which bleeding clearly did lead to Devin's dramatic symptoms of May 24, 1993, likely was *caused by* Devin's DPT inoculation on May 19, 1993. Accordingly, I have also considered whether petitioner has presented a meritorious "causation-in-fact" theory in this case.

It should be noted, initially, that in analyzing a contention of "causation-in-fact," the presumptions available under the Vaccine Injury Table are, of course, inoperative. It is clear that the burden is on the petitioner to show that in fact the vaccination in question more likely than not caused the injury. See, *e.g.*, *Hines v. Secretary of Dep't. of HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *Carter v. Secretary of Dep't. of HHS*, 21 Cl. Ct. 651, 654 (1990); *Strother v. Secretary of Dep't. of HHS*, 21 Cl. Ct. 365, 369-70 (1990), aff'd, No. 91-5030 (Fed. Cir. Nov. 15, 1991); *Shaw v. Secretary of Dep't. of HHS*, 18 Cl. Ct. 646, 650-1 (1989). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." *Strother, supra*, 21 Cl. Ct. at 370; accord, *Hines, supra*, 940 F.2d at 1525; *Carter, supra*, 21 Cl. Ct. at 654; *Hasler v. United States*, 718 F.2d 202, 205-6 (6th Cir. 1983); *Novak v. United States*, 865 F.2d 718, 724 (6th Cir. 1989). Temporal association alone is *not* sufficient. *Strother, supra*, 21 Cl. Ct. at 370; *Shaw, supra*, 18 Cl. Ct. at 650-651; *Carter, supra*, 21 Cl. Ct. at 654. Moreover, "similarity of petitioner's injury to injuries listed on the Table does not show causation in fact. Encephalitis, seizure disorders, and other Table injuries can have causes other than administration of a vaccine." *Strother, supra*, 21 Cl. Ct. at 370. Ct. at 370. (11)

It is clear in this case, however, that the petitioner has *not* been able to carry his burden as to "causation-in-fact." First, Dr. Schweller, whose efforts seemed to be chiefly directed toward supporting the "Table Injury encephalopathy" theory, never purported to state or explain any "causation-in-fact" theory that was separate or distinct from the Table Injury theory. That is, as explained above, Dr. Schweller's<sup>(12)</sup> sole stated theory of the case was that Devin began to experience new bleeding into the subdural space during the three-day post-inoculation period, which bleeding eventually caused the intracranial pressure that resulted in the symptoms of May 24, 1993. Dr. Schweller's "causation-in-fact" theory simply adds, to that same scenario, the opinion that the new bleeding began not only soon after the inoculation, but *as a result of* that inoculation. But I have rejected Dr. Schweller's theory that the bleeding likely began during that three-day period, for reasons set forth above. Thus, his "causation-in-fact" theory must fail for the same reasons that the "Table Injury encephalopathy" theory failed.

In addition, I might also add that Dr. Schweller's theory that the new bleeding was *caused by* the inoculation seems even more dubious than other aspects of his theory. Dr. Schweller acknowledged that there is *no* medical literature to support the theory that any element of the DPT vaccine can cause tissue in or near the brain to bleed, either in a normal brain or a brain that has already experienced a chronic subdural hematoma. Dr. Lockman, in response, testified that he had no idea how a DPT vaccination might cause such bleeding. I find that Dr. Schweller's theory in this regard amounts to no more than mere speculation.

I add one final note with respect to this "causation-in-fact" issue. It is, of course, not respondent's burden to show some other cause of Devin's injury, but rather the petitioner's burden to show causation by the

vaccination. The petitioner has failed to carry that burden in this case, so there is no need for me to affirmatively determine a cause of Devin's injury, and I do not purport to do so. However, it is obvious that the record of this case is replete with evidence pointing towards some type of head trauma, accidental or intentional, as a likely cause for Devin's injury. The evidence in that regard that I summarized at pp. 7-8, *supra*, is equally applicable on this point. (13) As I evaluate the record, the evidence pointing to trauma as the cause of Devin's injury is simply far superior to the scant evidence (consisting of little more than Dr. Schweller's speculative opinion) pointing to his vaccination. (14)

In short, for all the reasons set forth above, petitioner has failed to demonstrate entitlement to a Program award via the "causation-in-fact" route.

## VII

## **CONCLUSION**

The story of the brain injury of Devin Johnson is obviously a tragic one. Congress, however, designed the Vaccine Program to compensate only those individuals who can demonstrate either a causal or temporal link between their injuries and a listed vaccination, and petitioner has failed to do so with respect to Devin's injury. Therefore, my Decision is that petitioner is not entitled to a

Program award. Accordingly, in the absence of a motion for review of this Decision timely filed under the Rules of this Court, the clerk shall enter judgment in conformance with this Decision.

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George L. Hastings, Jr.

Special Master

- 1. The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq*. (1994 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (1994 ed.).
- 2. Petitioner filed Exhibits 1 through 13 along with the petition, and further consecutively-numbered exhibits on various dates thereafter. Respondent filed Exhibits A through J on various dates. "Ex. \_\_" references will be to those exhibits.
- 3. Petitioner bears the burden of demonstrating the facts necessary for entitlement to a Program award by a "preponderance of the evidence." § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than not." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).
- 4. At the evidentiary hearing in this Program proceeding, held on February 24, 1997, petitioner's counsel initially represented that petitioner's sole theory was that of a *significant aggravation* of "encephalopathy" falling within the Vaccine Injury Table. Later, however, counsel asked me to consider whether petitioner had demonstrated the *onset* of a Table encephalopathy. Further, petitioner's expert in the course of the hearing in effect stated the opinion that the DPT inoculation *caused* Devin's brain injury of May 24, 1997,

- so I have also considered "causation-in-fact" as alternative means of demonstrating entitlement to a Program award.
- 5. And, of course, it would not have been necessary, in order to prove a "Table Injury," to demonstrate that the vaccination *caused* the rebleeding. That is, if Dr. Schweller could have convinced me that the new bleeding *did* start during the *three-day post-inoculation period*, that would have been enough to demonstrate a Table Injury. The burden would then have shifted to the *respondent* to demonstrate that something *other* than the vaccination caused that bleeding. However, for the reasons stated above, Dr. Schweller was unable to persuade me that the new bleeding began during the three-day post-inoculation period.
- 6. I recognize that in her affidavit filed in this proceeding, as well as in her testimony in the criminal trial of Devin's father, Devin's mother describes Devin as having "projectile vomiting" on *May 20*, 1993. (Ex. 6, para. 10; Ex. E, p. 43.) However, this assertion is *not* corroborated by the medical records, which describe only one vomiting incident, which occurred on the morning of May 23, as "projectile" in nature. (See Ex. 9, pp. 14, 16, 18, 34; Ex. 10, pp. 211, 247, 250.) Based upon the medical records, I find it likely that only the vomiting on the morning of May 23 was particularly forceful in nature.
- 7. Even the testimony of Devin's mother in the criminal trial acknowledges that some vomiting incidents were not forceful in nature. See Ex. E, pp. 64-65.
- 8. Petitioner's counsel also emphasized at the hearing the fact that on May 25, 1993, Devin's father reported that on May 23, Devin possibly experienced an episode of "stiffening." (See Ex. 10, p. 201--"? stiffening.") Of course, it is true that the symptom of "stiffening" can be an indication of brain abnormality in some circumstances. But May 23 is still well outside the three-day post-vaccination period. Moreover, as respondent's experts explained, the question mark in the notation means that the physician taking the history questioned whether any stiffening had in fact occurred. And as Dr. Chadwick explained, "stiffening" is a very non-specific symptom that can mean many different things, including simply the way that infants often stiffen or arch their backs when they are engaged in vigorous crying. I found persuasive the testimony of Drs. Chadwick and Lockman that evaluating this questionable report of stiffening in the context of the overall record, it seems unlikely that this report indicates that an encephalopathic process was underway in Devin even on May 23.
- 9. Petitioner's counsel pointed out at the hearing that at the criminal trial of Devin's father, a radiologist, Dr. Kispert, had testified that the bleeding could have occurred at any time within the seven days preceding May 27, 1993. (See Ex. E, pp. 349-350, 356.) But Dr. Kispert clearly was basing his opinion *solely* upon the MRI and CT images, not on the clinical history. Drs. Lockman and Chadwick, in contrast, were relying upon not only those images, but also upon other aspects of Devin's case, including the symptoms that Devin displayed on May 24 at the hospital. Accordingly, I do not find that Dr. Kispert's opinion contradicts that of Drs. Chadwick and Lockman in any way.
- 10. As to the issue of retinal hemorrhaging, at the evidentiary hearing, petitioner's counsel seemed to emphasize that Devin's treating opthalomologist, Dr. Miller, testified at the criminal trial of Devin's father that the retinal hemorrhages might not have been caused by intracranial pressure, but instead by attempts to perform cardiopulmonary resuscitation (CPR) on Devin. (See, *e.g.*, Ex. E, pp. 263, 281.) But Dr. Miller acknowledged that retinal hemorrhages caused by inexpert CPR would be a very rare phenomenon. (Id. at 268, 270.) Moreover, petitioner's own hearing expert, Dr. Schweller, seemed to disagree with Dr. Miller on this point, indicating his belief that the retinal hemorrhages were, as Drs. Chadwick and Lockman opined, a result of intracranial pressure. (Tr. 31.) After comparing Dr. Miller's testimony in the criminal trial transcript to the testimony of the other criminal trial experts and the three experts in this case, I am persuaded that the retinal hemorrhages likely were a result of intracranial pressure.

- 11. The legislative history confirms this interpretation of the statute, providing that "[s]imple similarity to conditions or time periods listed on the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation \* \* \* ." H.R. Rept. No. 99-908, 99th Cong., 2d Sess., pt. 1, at 15 (reprinted in 1986 U.S. Code Cong. and Admin. News at 6356).
- 12. I recognize that in addition to Dr. Schweller's opinion, petitioner has also filed Ex. 17, the opinion of neurologist Dr. Gerald Slater, which seems to indicate Dr. Slater's belief that the vaccination caused Devin's injury. Dr. Slater's reasoning is further explained in his testimony in the transcript of the criminal trial of Devin's father, contained at Ex. F, pp. 595-667. I have reviewed these materials, but I do not find Dr. Slater's opinion to be persuasive, either. Moreover, I have witnessed Dr. Slater's testimony in person in another Program case, and I simply did not find him to be an honest witness. Accordingly, I do not find that Dr. Slater's opinion adds any significant weight to petitioner's case.
- 13. In addition to the opinions of Devin's treating physicians that trauma was the cause of Devin's injury, set forth at p. 8 above, I also add that another of Devin's treating physicians, the neurologist Dr. Bailey, set forth the opinion that there is no medical validity to the theory that the DPT inoculation caused Devin's injury. (Ex. 11, p. 19.)
- 14. At the evidentiary hearing, petitioner's counsel emphasized the fact that there was no evidence of external skin damage or bruising of Devin's head, or of skull fracture. But a review of the record makes it clear that this circumstance certainly does not rule out trauma as a cause of Devin's injury. As Dr. Chadwick explained, as a result of the testing described in the medical article filed in this case as Ex. 27, it is now controversial whether serious brain damage can be done without an infant's head actually striking something--for example, by the mere "shaking" of a baby without any actual head impact. However, as Dr. Chadwick further explained, and as is confirmed by Ex. 27 and other articles in the record, there appears to be no dispute that serious brain injury to an infant *can* occur without bruising or skull fracture if the infant's head strikes a *soft* surface, such as a mattress. Accordingly, the possibility of trauma as the cause of Devin's injury remains a strong one despite the lack of skin bruising or skull fracture.

Further, as respondent's counsel emphasized, to argue that trauma likely caused Devin's injury is hardly to say that the verdict in the criminal trial of Devin's father was wrong. To reach a guilty verdict in that case, the factfinder was required to conclude *beyond a reasonable doubt* not only that trauma caused the injury, but that such trauma was intentional rather than accidental, and was inflicted by one particular person. Here, the issue is only whether trauma of *any* kind, accidental *or* intentional, likely caused the injury, and no such strict standard of proof is involved. Accordingly, I do not believe that the fact that I have given weight to the theory of causation by trauma in this case can reasonably be interpreted as inconsistent with the criminal case verdict.